UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/529,096	04/07/00	MARUYAMA T	07385.0007

HM12/0619

FINNEGAN HENDERSON FARABOW
GARRETT & DUNNER
1300 I STREET NW
WASHINGTON DC 20005-3315

EXAMINER	
PATEL, S	
ART UNIT	PAPER NUMBER
1624	10

DATE MAILED: 06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/529,096	Tatsuya Maruyama et al.
Examiner	**Art Unit**
Sudhaker Patel	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 7, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-7 and 9-13* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7 and 9-13* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

The claims pending in this application are claims 1-7,9-13.

Applicants' communication paper #8 dated 5/7/01 is acknowledged.

This application has been found to lack unity of invention. Applicants traverse on the grounds that the allowable claims and compounds of the elected Group are not identified and therefore, the restriction requirement is inappropriate.

This is not found persuasive because the claims lack unity of invention. The claims lack unity of invention because compounds of generic Formula of claim 1 and its intermediates as recited do not possess single structural element that is shared by all of the alternatives that is inventive. The Formulae arrived at by computing values of Z, R2 A, R1a,R1b, B etc. which simultaneously represent multiples of compounds including heterocycles. Additionally the change(s) in heterocycle size simultaneously vary the molecule because of optionally fused feature with a benzene ring.. Therefore, these compounds do not share a common structural feature(s) , and only common properties shared by all the compounds is presence of : ***Heterocycle-C(H)OH-CH2-CH2-O-PH-NH-CO-X-B bridge*** which does not represent patentable advances over the prior art already known(see U.S.P. 5223614;WO 9529159)

Note that compounds, corresponding compositions, a method of use and the first recited process of making composition(s) that are of the same scope are considered to form a single inventive concept under PCT Rule 13.1, 37 CFR 1.475(d). The species as presented by various groups and either compounds or their derivatives as recited by generic Formulae are not so

linked as to form a single inventive concept. The compounds are so diverse in scope that a prior art of making it or its composition and using the same further as a pharmaceutical which is anticipated under 35 U.S.C. 102 would not render obvious another compound of the same claim 35 U.S.C. 103.

The Examiner finds Applicant's arguments not persuasive concerning traversal of the restriction; therefore, the finding is maintained and made **FINAL.** Applicants are required to confirm their election, and also to cancel the non elected subject matter in the next communication.

Furthermore, according to 37 CFR 1.499(see MPEP 1893.03(d)), the examiner may in office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted, if the Examiner finds that a national stage application lacks unity of invention under CFR 1.475.

Applicants' various remarks and arguments have been favorably considers, and the rejections under 35 U.S.C. 102 are withdrawn as the JP 10218861 publication date is 8/18/98 which is after the instant application' filing date 10/17/97.

The rejections made under U.S.C. 35 103(a) ref. Toshiyuki et al. are also withdrawn because the ref. does not teach pharmaceutical use.

However, following new grounds of rejections are still maintained.

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-7,9-13 are rejected under 35 U.S.C. 112, second para. as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

A). The generic claim 1 presents group B as: " heteroaryl group which may be substituted or unsubstituted and is optionally fused with a benzene ring". This is indefinite and vague because we are not told about the various substituents and their exact position for attachment to the ring.

Also, we do know exactly which kind of rings with which size, and the heteroatoms if any how many are involved by such indefinite definition.

B). The claims usually begin with " An amide derivative". This is indefinite because we do not know exactly which derivative.

"A compounds of Formula(I)" is suggested.

C). E claims' language also often recites the word "optionally" which is indefinite because we do not know exact point of attachment and connection to the ring carbon atom where applicable.

Claim Rejections - 35 U.S.C. § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7,9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.P. 5223614 to Schromm et al.

The applicants claim generically substituted amides of Formula(I) wherein B + heteroaryl group which is (UN) substituted and is optionally fused with a benzene ring., and further ring B optionally bonding with the lower alkyl group.

Applicants further claim composition comprising these compounds or the salt thereof in a pharmaceutically acceptable carrier, and a method for treating diabetes mellitus, obesity etc, in a human or animal patient in need of such treatment. The ref. '614 teaches generic compounds of the general Formula (I) (see abstract), and also Formula (Ia) (see column 1 lines 47-68, and column 2 lines 1-68) where in Formula (Ia) -R7- = -Ar-B-E (B =-NH-CO-C1-4 alkylene; E = -Het N+-; see column 3 lines 30-45), useful as pharmaceuticals, particularly for inhalation.. Claim 1 in the instant application differ from the reference by reciting more limited subgenus, however it is obvious to a chemist skilled in the art to select any species of the genus that will have reasonably similar properties and equal or better pharmaceutical use. The requisite motivation

stems from the expectation that compounds so structurally similar would be expected to possess similar properties(in re Wood, 199 USPQ 137).

It has been held that a prior art disclosed compounds is sufficient to render a prima facie case of obviousness as species falling within a genus. See In re SUSI, 440 F 2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by Federal Circuit in Merck & co. V. Biocraft Laboratories, 847 F 2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir.1989).See In re Dillon 16 USPQ 2nd. 1897, 1923 regarding a prima facie case of obvious ness of structurally similar compounds disclosed by prior art" regardless lo the properties disclosed in the inventor's application.

All this is especially considered so in the absence of timely, verified, comparative data, commensurate in scope to the claims sought, clearly and convincingly proving obvious ness over the art(s) as applied above. If applicants intend to rely on unusual or unforseen results demonstrate patentability, attention is drawn to MPEP 716. It is also pointed out that arguments of patentability to differences either not in, or not made clear by, claim language will be of no avail as it is the claims, per se, that are the measure of the invention.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

This application has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is, therefore, requested in promptly correcting any errors of which they may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel,D.Sc.Tech. whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr.Mukund Shah can be reached at (703) 308 4716.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

S.p.

June 18, 2001.

Mukund J. Shah

Mukund Shah

SUPERVISORY PATENT EXAMINER

ART UNIT 1624